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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,818	04/17/2001	Kelvin G.M. Brockbank	105452	5532

25944 7590 10/21/2002

OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

SANDALS, WILLIAM O

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/21/2002 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/835,818

Applicant(s)

Brockbank et al.

Examiner

William Sandals

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 31, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Apr 17, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 & 6 6) ☐ Other:

HRG
DTH 17

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II, claims 11-19 in Paper No. 10, filed July 31, 2002 is acknowledged. The traversal is on the ground(s) that the process could not be used with other cryopreservatives that there is no serious burden on the examiner if restriction is not required. This is not found persuasive because the process is not restricted to cyclohexanediol, but merely requires that at least one cyclohexanediol be present in the composition, and further, the process of cryopreservation is well known to be "practiced with another materially different product" as stated in the reasons for restriction. In addition, the composition of Group II may be used in a materially different process, such as use as a solvent for drugs, for example. The two groups are classified in different classifications, demonstrating the necessity for a different search, making the burden unreasonable.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group I, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8, mailed June 17, 2002.

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Drawings

3. The drawings as submitted on April 17, 2001, have been approved by the draftsman.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites “the group consisting of the cis or trans forms of 1, 3 cyclohexanediol and 1, 4 cyclohexanediol, and racemic mixtures thereof”. The term “cis or trans forms of 1, 3 cyclohexanediol and 1, 4 cyclohexanediol” is not clear. The “or” followed by the “and” confuses the intention of whether each of the “cis or trans 1, 3 cyclohexanediol and 1, 4 cyclohexanediol” are to be present separately or together in the composition. Also, it is not clear if one of the “1, 3 cyclohexanediol and 1, 4 cyclohexanediol” may be in cis while the other may be in trans. “Racemic mixtures thereof” is also confusing, since it is not clear if both of the “1, 3 cyclohexanediol and 1, 4 cyclohexanediol” must be in the claimed mixture. Finally, “cis and trans” are the intended ‘racemic’ forms, therefore the recitation of “cis and trans” followed by the recitation “racemic” suggests that “cis and trans” and “racemic” each have a separate meaning.

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Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/18169 (of record).

WO 99/18169 teaches at pages 19, 24-25, in the figures and in the claims, a cryopreservation composition comprising at least one cyclohexanediol and at least one additional cryoprotectant compound. The use of cis, trans and racemic mixtures is discussed. Molarities are within the recited ranges and additional cryoprotectant compounds are recited.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/18169 in view of US 6,395,467 (Fahy et al.).

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The claims are drawn to a cryopreservation composition comprising at least one cyclohexanediol and at least one additional cryoprotectant compound. The cyclohexanediol may be 1, 3 cyclohexanediol or 1, 4 cyclohexanediol in cis or trans, or mixtures thereof. The cyclohexanediol may be from 0.05-2 Molar, the additional cryoprotectant compound may be from 0.1-10 Molar. The additional cryoprotectant compound may be those recited in claim 14. The composition may further comprise at least one antifreeze protein, which may be an antifreeze glycoprotein in the range of 0.01-1 Mg/ml.

WO 09/18169 teaches the claimed invention as described in the rejection under 35 USC 102 above. WO 99/18169 also teaches at page 2 the well known antifreeze proteins and antifreeze glycoproteins. The antifreeze proteins are taught to be used in the claimed range of molarity.

WO 09/18169 did not teach that the composition may further comprise at least one antifreeze protein or antifreeze glycoprotein in the range of 0.01-1 Mg/ml.

Fahy et al. teach at column 6, lines 8-23 and at the claims, the useful addition of antifreeze proteins to a cryopreservation composition containing at least one other cryoprotectant. The antifreeze proteins are taught to be used in the claimed range of molarity.

It would have been obvious to one of ordinary skill in the art at the time of filing the instant application to combine the teachings of WO 99/18169 with Fahy et al. to produce the instant invention because WO 99/18169 teaches the advantageous use of cyclohexanediol in a cryopreservation composition containing at least one other cryoprotectant, and Fahy et al. teach

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the advantageous use of an antifreeze protein in a cryopreservation composition containing at least one other cryoprotectant. Both WO 99/18169 and Fahy et al. teach the combination of at least two cryoprotectants in a cryopreservation solution. It would therefore be obvious one of ordinary skill in the art to combine cryoprotectants which are known to function in cryopreservation compositions.

One of ordinary skill in the art would have been motivated to combine the teachings of WO 99/18169 with Fahy et al. to produce the instant invention because Fahy et al. state at column 7, lines 43-46 and column 8, lines 11-14 that there is a desirable and useful benefit to adding antifreeze proteins to a cryopreservation composition containing at least one other cryoprotectant compound, because antifreeze proteins provide cold protection not afforded by other cryoprotectants. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of WO 99/18169 with Fahy et al.

Conclusion

10. Certain papers related to this application are ***welcomed*** to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or

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applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

October 18, 2002


TERRY MCKELVEY
PRIMARY EXAMINER